REMARKS

Claims 1, 4-22, 24, and 26-62 remain in the application. Claims 1, 4, 6, 9, 22, 28, 29, and 51 have been amended. Reconsideration of this application, as amended, is respectfully requested.

Claims 1, 4, 6, 9, 22, 28, 29, and 51 have been amended to specify that the indicator on the test strip select only one of a multiplicity of testing functionalities of the measuring device. Support for these amendments can be found at the following locations in the specification:

page 9, lines 3-14;
page 9, lines 19-22;
page 10, lines 2-4
page 10, lines 15- 17;
page 11, lines 4-7;
page 11, lines 15-19;
page 11, lines 20-23;
page 12, lines 18-20;
page 13, line 29 through page 14, line 2;
page 14, line 20 through page 15, line 18.

Because the foregoing amendment touches the merits of the application, a showing under 37 C.F.R. 1.116(c) is expected. The amendment is necessary to overcome the rejections based on Allen and Gunasingham. The amendment was not earlier presented because the undersigned had the bona fide belief that the term "one" meant "only one." The present amendment is being presented at this time because the claims, if amended as proposed, would avoid the rejections based on 35 U.S.C. § 102, and thus the amendment would place the case in condition for allowance or in better condition for appeal. The claims, if amended as proposed, would avoid the rejection on the references. In view of the foregoing reasons, the Examiner has sufficient grounds for entering the amendment.

Claims 1-3, 9, 10, 12-18, 21-24, 27, and 28 stand rejected under

35 U. S. C. § 102 (b) as being anticipated by U S Patent 5,580,794 to Allen. This rejection is respectfully traversed for the following reasons.

Allen, U. S. Patent No. 5,580,794 (hereinafter "Allen"), discloses a disposable electronic assay device comprising card-like housing containing a sample receptor means for receiving a sample of body fluid containing an analyte to be determined, a sample treatment means for reaction with sample fluid components to yield a physically detectable change which correlates with the amount of analyte in the sample, a detector means responsive to the physically detectable change for producing an electrical signal which correlates with the amount of analyte in the sample, signal processing means connected to the detector means for converting the electrical signal to a digital test result output, and visually readable output means connected to the signal processor means for receiving and presenting the test result output.

The present invention provides products wherein a user may perform a multiplicity of different assays with a single measuring device having a multiplicity of testing functionalities, without the need for manually reconfiguring or switching between different functionalities of the device. By eliminating the need for the user to manually set the device when changing from one testing functionality to another, the invention provides increased convenience and speed of use, and reduces the likelihood of human error. The invention employs a test port that is capable of recognizing various diagnostic test strips having different testing functionalities, e.g., glucose, ketone bodies. Each type of diagnostic test strip comprises a different indicator (or indicators) that enables the test port to differentiate one type of diagnostic test strip from another type of diagnostic test strip. When the user inserts a diagnostic test strip into the test port of the measuring device, the test port will identify the appropriate functionality of the measuring device and automatically reconfigure or switch the measuring device to the appropriate functionality. See page 7, lines 3-17 of the specification. Specific types of indicators are described at page 9, line 27 through page 11, line 7 of the specification. Test ports for interacting with the diagnostic test strips are described at page 11, line 9 through page 12, line 20 of the specification. Neither of the references relied on by the Examiner disclose or suggest the test strips or the test ports of the type claimed in this application.

At column 6, lines 48-52 of Allen, it is stated:

> Single or multiple assays can be done at one time. For example, a single assay can be done measuring cholesterol or one device can be set up to measure both total and HDL cholesterol from a single sample. One test device can be set up to measure one, two, three, or more analytes **at one time**. (emphasis added)

This statement does not disclose or suggest an indicator on a test strip that can allow a measuring device to differentiate between two or more types of test strips (e.g., glucose, ketone bodies) to select one and only one (e.g., glucose) of a multiplicity of testing functionalities of the measuring device. This statement does not disclose or suggest a test port (of a measuring device) having a sensor that can select one and only one (e.g., glucose) of a multiplicity of testing functionalities of the measuring device. This statement does not disclose or suggest that that the measuring device and the test strips described in Allen can cooperate to differentiate between two or more types of assays, but must perform all of the assays on a test strip at the same time. In Example 1 of Allen, it is shown that more than one assay on the test strip can be carried out at the same time. However, the test strip and the test port in Allen cannot communicate to select only one assay from a multiplicity of assays to be performed at a particular time. In Allen, all of the assays in a given set of assays must be carried out at the same time. In view of the foregoing, it is submitted that Allen does not anticipate any claim of this application. It should be noted that claims 1, 4, 6, 9, 22, 28, 29, and 51 have been amended to change the phrase " thereby selecting one of said multiplicity of testing functionalities of said measuring device" to "to thereby select only one of said multiplicity of testing functionalities of said measuring device."

Claims 1-8, 10-22, 24, 26, and 28-62 were rejected under 35 U. S. C. § 102 (b) as being anticipated by US Patent 5,312, 590 to Gunasingham. This rejection is respectfully traversed for the following reasons.

Gunasingham, U. S. Patent No. 5,312,590 (hereinafter "Gunasingham"), discloses a method and apparatus for measuring a wide range of chemical species in liquids. The apparatus employs a flat test device comprising a number of symmetrically arranged sensor elements that enable the multi-species determination from a single sample drop. Each sensor element is coated with a unique reaction layer that makes it responsive to specific chemical species. Additionally, all the sensor elements are coated with a single membrane which serves the dual function of a diffusion barrier and filter. An insulating layer is further coated over the membrane with specific provision for wells where the sample and reference solutions may be placed. In a preferred embodiment of the invention, the sample well is centrally located so that chemical species present in the sample can diffuse equally to the various sensing elements. The reference solution wells are located adjacent to the specific sensing element. The center of the sample solution well and the center of the reference solution well are equidistant to the respective sensing element so that the diffusion of chemical species from the sample and reference solutions occurs equally.

As stated previously, each type of diagnostic test strip claimed in the present application comprises a different indicator (or indicators) that enables the test port to differentiate one type of diagnostic test strip from another type of diagnostic test strip. When the user inserts a diagnostic test strip into the test port of the measuring device, the test port will identify the appropriate functionality of the measuring device and automatically reconfigure or switch the measuring device to the appropriate functionality.

At column 8, lines 24-44 of Gunasingham, multi-species detection was described as follows:

> The device consists of four symmetrically arranged sensor elements (16) that enable multi-species determination from a single sample drop. Each sensor element is coated with a unique reaction layer (17) that makes it responsive to specific chemical species. Additionally, all the sensor elements are coated with a single membrane (18) which serves the dual function of a diffusion barrier and filter. An insulating layer (19)

is further coated over the membrane with specific provision for wells where the sample (20) and reference solutions (21) may be placed. The sample well is centrally located so that chemical species present in the sample can diffuse equally to the various sensing elements. The reference solution wells are located adjacent to the specific sensing element. The center of the sample solution well and the center of the reference solution well are equidistant to the respective sensing element so that **the diffusion of chemical species from the sample and reference solutions occurs equally**. (emphasis added)

This statement does not disclose or suggest an indicator on a test strip that can allow a measuring device to differentiate between two or more types of test strips (e.g., glucose, ketone bodies) to select one and only one (e.g., glucose) of a multiplicity of testing functionalities of the measuring device. This statement does not disclose or suggest a test port (of a measuring device) having a sensor that can select one and only one (e.g., glucose) of a multiplicity of testing functionalities of the measuring device. This statement does not disclose or suggest that the measuring device and the test strips described in Gunasingham can cooperate to differentiate between two or more types of assays, but must perform all of the assays on a test strip at the same time. In Example 4 of Gunasingham, it is shown that more than one assay can be carried out at the same time. However, the test strip and the test port in Gunasingham cannot communicate to select only one assay from a plurality of assays to be performed at a particular time. In Gunasingham, all of the assays in a given set of assays must be carried out at the same time. In view of the foregoing, it is submitted that Gunasingham does not anticipate any claim of this application. It should be noted that claims 1, 4, 6, 9, 22, 28, 29, and 51 have been amended to change the phrase " thereby selecting one of said multiplicity of testing functionalities of said measuring device" to "to thereby select only one of said multiplicity of testing functionalities of said measuring device."

In view of the foregoing, it is submitted that claims 1, 4-22, 24, and 26-62, as amended, are in condition for allowance, and official Notice of Allowance is respectfully requested.

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Respectfully submitted,
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